

Concurrent chemoradiation (CChRT) for locally advanced stage III non-small cell lung cancer (NSCLC) with cisplatin and vinorelbine and thoracic radiotherapy: A phase II study from the Galician Lung Cancer Group.

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Background:

Platinum-based CChRT is recommended as the evidence-based approach for the management of patients (p) with locally advanced stage III NSCLC and a good performance status, although a clearly superior regimen has not been identified. The aim of our study was to evaluate the effectiveness and toxicities of CChRT with Cisplatin (C) and intravenous and oral vinorelbine (V) and thoracic radiotherapy.

Methods:

39 p with histologically confirmed inoperable locally advanced NSCLC, stage IIIA (T4 or N2)/IIIB, PS 0-1 and adequate lung function (FEV1 > 1.1, V20 < 30%) were included in CChRT with: C 80 mg/m² day 1 and intravenous V 25 mg/m² day 1 and oral V 60 mg/m² day 8 for three cycles, during conformal radical thoracic radiotherapy (66 Gys, 180 cGy/day). The primary objective was overall survival (OS); secondary objectives were progression free survival (PFS), response rate (RR) and toxicity. Median follow-up: 20,4 months.

Results:

The p characteristics were: mean age 69,8 years (44-75); male/female: 33/6; ECOG PS 0/1: 7/32; adeno/squamous/large cell carcinoma: 20/13/6; stage IIIA 19 p and stage IIIB 20 p. All p were evaluable for response and toxicity. RR: 3 CR, 27 PR (RR 77%; 95% CI: 64-90), 5 SD (12.8%) and 4 PD (10.2%). The median PFS was 12 months (95% CI: 7-17) and median OS was 36 months (95% CI: 14-58). The PFS at 1

years were 46%/22% and the OS at 1/3 years were 75%/47%. Main toxicities (NCI-CTC 4.0) per p in CChRT (109 cycles of chemotherapy, 2.9 per p; mean doses RT: 65,3 Gys) grade 1-2/3-4 (%) were: neutropenia 32.4/25.6; anemia 32.4/10.8; thrombocytopenia 13.5/2.7; nausea/vomiting 27/2.7; fatigue 28.2/0; esophagitis 43.5/5.4 and pneumonitis 17.9/0; hospitalizations were necessary in 13 p: the most important were febrile neutropenia (6 p) and grade 3 esophagitis (2 p).

Conclusions:

CChRT with Cisplatin and intravenous and oral Vinorelbine during thoracic radiotherapy is a feasible treatment option for inoperable locally advanced stage III NSCLC, showing good clinical efficacy and tolerability with excellent long-term survival.

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